Attorney Docket No: MP/155

#9
B. Weble
12/3/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Krall et al.
Serial No. : 09/848,121
Filed : May 2, 2001
Title : Defibrillation Electrode Cover
Grp Art Unit : 3762
Examiner : Schaetzle, Kennedy

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on November 21, 2003.

Melanee Williams

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.131

Dear Sir:

I, Robert C. Krall, am an inventor of the present application. Prior to Dec. 28, 2000, I was directly involved in the making of defibrillation leads having thin, porous electrode cover. The work was performed in the United States. In particular, I was involved in the making of 17 such leads sent to another company for evaluation under confidentiality. This work is described in the photocopied page of the lab book attached as Exhibit A. The name of the other company is redacted. One of these 17 leads, No. 7109104572, was returned by the other company and retained by me as a sample. A photograph of the returned lead is provided as Exhibit B1; Exhibit B2 is a photograph of the electrode portion of this lead.

Each of these leads comprised coiled defibrillation electrodes provided with a thin (about 0.023mm thick) porous polymer covering, the covering material being porous expanded polytetrafluororethylene film. As determined by the method taught by the present specification at page 7, lines 14-33, the film had a pore size that would substantially preclude attachment of living tissue when implanted. The mean fibril length of this film (indicative of small pore size) was less than about 1.0 microns. The covering had been provided with a PVA wetting agent. Tests demonstrated that these leads were electrically non-conductive in a dry state and conductive when wet. Leads of this type exhibited no visually apparent mechanical disruption when viewed under 30X microscopy following testing in a saline solution with a series of biphasic single cycle voltage pulses. These leads were determined by in vitro testing to have a long fatigue life. Non-human implants of these leads demonstrated them to be effective defibrillation leads.

The declarant further states that the above statements were made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statement may jeopardize the validity of this application or any patent resulting therefrom.

November 20, 2003
Date:

Robert C. Krall
Robert C. Krall